1. (Amended) A system for simulating movement of a medical device in a body cavity or lumen of a patient, comprising:

   (a) a medical device comprising a first end for manipulation by a user and a portion comprising a second end insertable into a simulated body cavity or body lumen in a manikin; and

   (b) a manikin comprising an interface for receiving the portion comprising the second end and for interfacing with a simulated body cavity or lumen within the manikin, wherein the interface comprises a directional force feedback mechanism for exerting a directional force on the medical device in response to a feedback signal received by the force feedback mechanism;

   wherein the system models interactions between the device and the body cavity or lumen in three-dimensions.

11. (Amended) The system according to claim 9, wherein the manikin further comprises a tracking unit comprising a light source, a signal processing circuit, and one or more optical sensors, wherein the tracking unit is placed within the interface in optical communication with the device when it is inserted into the cavity or lumen.

21. (Amended, corresponds to second claim 20) The system according to claim 19, further comprising a simulated scanning display for displaying a two-dimensional image of the simulated body cavity or lumen.

22. (Amended, corresponds to original claim 21) The system according to claim 21, wherein the simulated scanning display is part of a simulated scanning device.

23. (Amended, corresponds to original claim 22) The system according to claim 22, wherein the simulated scanning device is simulating an x-ray imaging system.

24. (Amended, corresponds to original claim 23) The system according to claim 22, wherein the simulated scanning device and scanning display are coupled to a movable C-arm within scanning distance of the manikin.

25. (Amended, corresponds to original claim 24) The system according to claim 1, further comprising a re-configurable control panel for performing one or more of: image acquisition selection; image display; manipulating a table on which the manikin is placed; manipulating the position of a simulated scanning device relative to the manikin; and control of one or more shutter devices for limiting a field of view of a scanning device placed within scanning distance of the manikin.

26. (Amended, corresponds to original claim 25) The system according to claim 1 or 20, further comprising a monitoring station, the monitoring station comprising a second user device connectable to the network and comprising a second display interface for enabling a second user to monitor the movement of the medical device within the simulated body cavity or lumen.

27 (Amended, corresponds to original claim 26) The system according to claim 26, wherein the second display interface of the monitoring station displays selectable options enabling the second user to select or change one or more anatomical and/or physiological parameters of the simulated body cavity or lumen, and wherein the selection causes the three-dimensional image of the simulated body cavity or lumen displayed to the first user

to change to reflect the changed anatomical and/or physiological parameters.

28. (Amended, corresponds to original claim 27) The system according to claim 20, wherein the system is connectable to a database of patient images and/or medical data.

29. (Amended, corresponds to original claim 28) The system according to claim 26, wherein the system is connectable to a database of patient images and/or medical data.

30. (Amended, corresponds to original claim 29) The system according to claim 28, wherein the patient images comprise images of a body cavity or lumen from a patient affected by a pathology.

31. (Amended, corresponds to original claim 30) The system according to claim 29, wherein the patient images comprise images of a body cavity or lumen from a patient affected by a pathology.

32. (Amended, corresponds to original claim 31) The system according to claim 22, further comprising at least one foot-activation switch for activating or collimating the simulated scanning device, image display or table movement.

33. (Amended) The system according to claim 28, wherein the first user display interface provides access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the first user display interface.

34. (Amended) The system according to claim 28, wherein the second user display

interface provides access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the second user display interface.

38. (Amended) A syringe for simulating fluid delivery, comprising:

a housing defining a lumen comprising an opening for delivering a fluid;

a pushing element for pushing the fluid through the opening;

a friction-producing element within the lumen of the housing in communication with the pushing element; and

a motor within the lumen of the housing and in communication with the friction-producing element and comprising a signal-receiving element,

wherein the friction-producing element causes friction between the pushing element and a surface of the lumen of the housing upon activation of the motor in response to a signal received by the signal-receiving element.

44. (Amended) The system according to claim 1, further comprising a syringe for simulating fluid delivery, the syringe comprising:

a housing defining a lumen comprising an opening for delivering a fluid;

a pushing element for pushing the fluid through the opening;

a friction-producing element in communication with the pushing element; and

a motor in communication with the friction-producing element and comprising a signal-receiving element,

wherein the friction-producing element causes friction between the pushing element and a surface of the lumen of the housing upon activation by the motor in response to a signal received by the signal-receiving element, and further

wherein the opening of the syringe is connectable to a connecting piece

having a first end for receiving fluid from the opening and a second end for delivering fluid to a simulated body cavity or body lumen in the manikin.

45. (Amended) A balloon-inflating device for simulating deployment of a balloon within a body cavity or lumen of a patient, comprising:

a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon;

a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device;

an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor and an automatic control system for controlling the amount of pressure delivered to the balloon.

46. (Amended) The system according to claim 1, further comprising a balloon-inflating device for simulating deployment of a balloon within the body cavity or lumen of the patient, the balloon-inflating device comprising:

a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon;

a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device;

an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor.

65. (Amended) A method for simulating deployment of a balloon within a body cavity or lumen of a patient, comprising:

(a) providing a balloon-inflating device, comprising:

a delivery mechanism for controlling delivery of a fluid through the balloon-inflating device to the balloon;

a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device;

an electrical pressure meter for reading pressure determined by the pressure sensor and for transmitting a signal corresponding to a pressure value to a processor; and

an automatic control system for controlling the amount of pressure delivered to the balloon;

(b) providing a system comprising:

a processor for receiving the signal, the processor connectable to the network; and

a user device comprising an interface displaying a representation of the balloon within a simulated body cavity or lumen; and

(c) delivering the fluid to the balloon; wherein deployment of the balloon in response to the delivering is displayed on the user device.

74. (New) A system for simulating movement of a medical device in a body cavity or lumen of a patient, comprising:

(a) a medical device comprising a first end for manipulation by a user and a portion comprising a second end insertable into a simulated body cavity or body lumen in a manikin; and

(b) a manikin comprising an interface for receiving the portion comprising the second end and for interfacing with a simulated body cavity or lumen within the manikin, wherein the interface comprises a feedback mechanism for providing continuous vibrational feedback to the medical device.

75. (New) A system for simulating movement of a medical device in a body cavity or lumen of a patient, comprising:

(a) a medical device comprising a first end for manipulation by a user and a portion comprising a second end insertable into a simulated body cavity or body lumen in a manikin;

(b) a manikin comprising an interface for receiving the portion comprising the second end and for interfacing with a simulated body cavity or lumen within the manikin; and

(c) a processor for simulating real-time movement of the medical device with a simulated body cavity or lumen, wherein deformation of the simulated body cavity or lumen in response to blood flow or the movement of the medical device is modeled in real-time.

Pending claims

Claims 1-73 are pending in the application. Upon entry of this Amendment, claims 1, 11, second claim 20, 21 - 31, 33, 34, 38, 44, 45, a and 65 are amended and claims 74 and 75 are added. A clean copy of claims 1-75 as presented for examination is provided.

No new matter is added by this amendment. Support for the added claims is found throughout the specification, and at least in the claims as originally presented, as well as at pages 31-33 of the specification.

Objection Regarding Misnumbered Claims

The Examiner has objected to certain claims for being improperly numbered. Applicants thank the Examiner for drawing this to their attention and have renumbered the claims. Accordingly, Applicants respectfully request that the objection be reconsidered and withdrawn.

Objection Regarding Improper Multiple Dependent Claims

The Examiner has objected to claims 44 and 46 as being in improper form. Applicants respectfully submit that the objection is moot in view of the amendments to claims 44 and 46 and respectfully request that the objection be reconsidered and withdrawn. Applicants note that the Examiner has treated claim 46 on the merits in the Office Action.

Rejection of Claim 66 Under 35 U.S.C. § 112 Second Paragraph

Claim 66 is rejected under 35 U.S.C. § 112, second paragraph for failing to particularly point out and distinctly claim the invention. The Examiner asserts that the claim is indefinite for reciting, "...wherein the fluid is air", because air is a gas not a fluid.

Applicants respectfully traverse the rejection. Air is a gas that is an example of a pneumatic fluid (see, Exhibit A). Accordingly, Applicants respectfully submit the rejection is improper and should be withdrawn.

Rejection of Claims 38-44 Under 35 U.S.C. § 102(b)

Claims 38-44 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,704,791 by Gillio, et al. ("Gillio"). The Examiner asserts that claims are anticipated by Figures 1 and 14 and Gillio's disclosure at column 6, line 61 through column 7, line 20 and at column 14, line 41 through column 15, line 34, which the Examiner asserts discloses each of the elements of the claims.

Applicants respectfully traverse the rejection. Figure 1 merely shows a tube 108 that is purported to simulate a generic medical device. Nowhere in columns 6 or 7 referring to Figure 1, is a syringe described. Gillio discloses that rollers can be provided *outside of* the tube (see Figure 4, details 230, 232, 234, and 236) and that these rollers can be equipped with stepper motors (column 7, lines 12-14). Nowhere does Gillio describe a motor comprising a signal-receiving element that causes friction between a friction-producing element in a syringe and the surface of a lumen in the syringe.

Figure 14 and the disclosure at columns 14 and 15 do not remedy this deficiency. Figure 14 shows a hose (904) for receiving an instrument. In Figure 14, forceps 914 are inserted into an opening of the hose. At column 15, line 1-16, Gillio discloses that the forceps might be replaced with a syringe handle. However, Gillio does not disclose providing the remainder of a syringe (e.g., a syringe body). Further, Gillio does not teach a motor comprising a signal-receiving element. Rather, Gillio discloses only that signals may somehow emanate from a biopsy forceps placed in the hose (see, e.g., column 14, lines 55-59) and that these signals are provided to a

computer. Even assuming *arguendo* that the hose is somehow analogous to a syringe body in this system, and that the biopsy forceps is interchanged with a syringe handle, Gillio does not disclose increasing friction between a friction producing element and surface of a lumen in a syringe in response to a signal received by a motor in communication with the friction-producing element. There is simply no motor in the system exemplified in Figure 14, nor is there any suggestion to provide such a motor or to couple it to a friction-producing element.

Additionally, even if one were to somehow combine the tube simulating a medical device in Figure 1 with the hose for receiving an instrument of Figure 14, this does not generate the syringe claimed in claim 38 or in any of its dependent claims. The motors associated with the rollers outside of the tube in Figure 1 are not designed to alter friction between a pushing element such as a syringe handle and the inner surface of the tube.

Accordingly, because Gillio does not disclose all of the elements of the claims, Gillio does not anticipate the claims. Therefore, in view of the above arguments, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Rejection of Claims 45 and 65-67 Under 35 U.S.C. § 102(b)

Claims 45 and 65-67 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,106,301 by Merril ("Merril"). The Examiner asserts that Figures 1-5 and columns 5 (lines 43-57), column 6, line 45, through column 7, line 16, and column 14, line 20 through column 16, line 41 of Merril disclose each of the elements of the claims.

Applicants respectfully traverse the rejection. Merril does not disclose an electrical pressure meter for reading pressure determined by a pressure sensor. At column 16, lines 25-41,

Merril discloses using a strain gauge to measure pressure caused by inflation of a balloon. The strain gauge is described as a band of a sturdy material such as aluminum formed in the shape of a ring having pressure sensors disposed about the ring. The strain gauge disclosed by Merril is a mechanical monitor of pressure change sensed by the sensors rather than an electrical pressure meter. Further, Merrill does not teach an interface which comprises a control device for controlling the amount of pressure delivered to the balloon as recited in the amended claims.

Accordingly, because Merril does not disclose all of the elements of the claims, Merril does not anticipate the claims. Therefore, in view of the above arguments, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Rejection of Claims 1-6, 9-37, 46-63 and 69-73 Under 35 U.S.C. § 103(a)

Claims 1-6, 9-37, 46-63 and 69-73 are rejected under 35 U.S.C. § 103(a) as being obvious over Merril in view of Gillio. The Examiner acknowledges that Merril does not teach a housing comprising a manikin or a medical device having a second end insertable into a simulated body cavity or lumen in a manikin, the manikin having an interface for receiving the second end. However, the Examiner asserts that these features are obvious in view of Gillio.

Applicants respectfully traverse the rejection.

None of the Figures or sections cited by the Examiner disclose or suggest the use of a manikin. In fact, Merril teaches away from the use of a manikin, believing that systems utilizing manikins *degrade the realism* of a simulation and restrict training of a medical procedure to a particular bodily region or arterial paths defined by the manikin (see, column 2, line 62, through column 3, line 8). Therefore, Merril provides no suggestion or motivation to modify the system taught by Merril to include such a manikin, since Merril does not view use of a manikin

appropriate to enhance the realism of a simulated procedure. Merril specifically comments that the system of Hon referred to by the Examiner *is undesirable* (see, *Id.*)

Merril does not teach a directional force feedback mechanism that provides resistance to forward motion but enables free reverse motion in response to the feedback signal as recited in claims 2 and 52. The Examiner asserts that this feature is effectively a spring and that such a force feedback mechanism would be obvious in view of Merril's general disclosure of simulating a medical procedure.

As a first matter, Merril does not even teach a spring and nowhere suggests using a spring to provide directional force feedback as recited in the claims. Merril's sole disclosure of feedback relates directs the ordinary artisan to provide a feedback unit on the medical instrument itself, i.e., *along the orthogonal axis* of the instrument. Merril's general aspiration to provide a realistic simulation does not provide the requisite motivation to modify his system to include such a spring, much less to employ a spring to provide resistance to forward motion while enabling free reverse motion in response to the feedback signal.

However, even assuming *arguendo* that Merril taught a spring, such an element would not be a directional force feedback system for exerting a directional force on the medical device in response to a feedback signal received by the force feedback mechanism. While a spring may have three-dimensional coordinates, it is a one –dimensional model. The force that could be felt on compressing a spring is essentially uniaxial. As shown in Figure 1 below, a spring is an elastic material which behaves in accordance with Hooke's Law. The push (F) and pull (P) forces are equal in magnitude but opposite in direction.

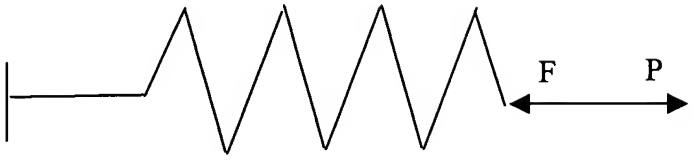

Figure 1. A spring model

A spring does not provide directional force feedback which provides resistance in a forward dimension and allows for *free movement* in the reverse direction since a spring exerts a push force in the reverse direction of equal magnitude in to the push force in the forward direction. Additionally, Merrill neither discloses nor suggests a system which models interactions between a medical device and a body cavity or lumen in a patient in three-dimensions, as illustrated in Figure 2 below and discussed in the specification at pages 29 – 33.

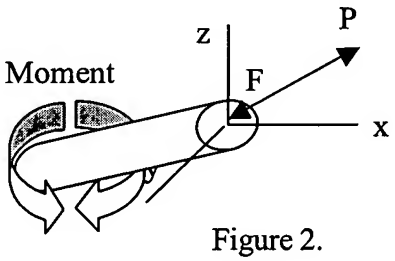

Figure 2.

To the extent that Gillio reports the use of a spring in association with a joystick (Figure 7), Gillio's system does not disclose or suggest modeling interactions between a medical device and body cavity or lumen in three-dimensions and thus Gillio's system does not provide a way to compute the moment along the axis of a medical device in response to directional feedback from a device in an interface of any kind, much less a manikin. Neither Gillio nor Merril disclose or suggest modeling interactions between a medical device and a body cavity or lumen of a patient in three dimensions.

Having previously acknowledged that Merril does not disclose either a manikin or directional force feedback, the Examiner then asserts at page 9 of the Office Action that Merril "teaches a directional force feedback mechanism comprising a rolling element coupled to the portion of the device comprising the second end and wherein tan internal surface of the simulated cavity or lumen in the manikin comprises an oblique slot for receiving the rolling element", asserting that Figures 1-3 support this proposition.

As discussed above, Merril does not disclose or suggest a manikin or directional force feedback. Although Merril discloses the use of rollers, nowhere does Merril disclose the combination of a rolling element coupled to the second end of a simulated medical instrument or a surface comprising an oblique slot for receiving the rolling element, much less a surface in a manikin.

The Examiner additionally asserts that the forward movement of a rolling element into an oblique slot in response to a feedback system is disclosed at Figures 1-5 and at column 18, lines 28-67. The cited sections of Merril do not support this proposition. In contrast, the only "slots" disclosed in Merril at column 18, lines 53-56, are described as being parts of encoder disks and are provided for the purpose of enabling light to be detected by an encoder photodetector. Id.

Additionally, Merril's system does not provide for continuous tracking. With the tracking methods described by Merrill, the user will have to pull back the simulated medical devices with the system paused so as to give more length to the device. The user also would have to push the device further in so that the tracking of the medical devices can be engaged. A continuous tracking system according to one aspect of the invention is shown in Figure 3 below. The device does not pause during tracking thus providing for more realistic tracking behavor.

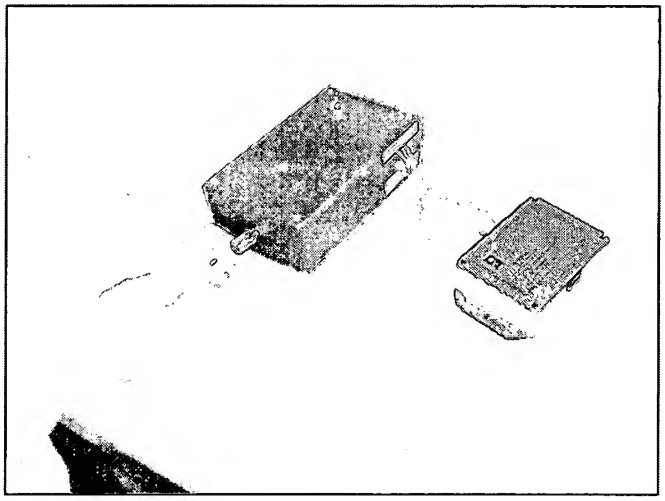

Figure 3

Additionally, contrary to the Examiner's assertion, Merril does not disclose or suggest a laparoscope, bronchoscope, coil, vascular occlusion device, or an optical coil short of generally disclosing "a medical device". Merril does not provide any teaching as to how to simulate such devices or how to model their interactions with a body cavity or lumen.

With regards to the Examiner's assertions regarding claims 18 and 19, as discussed above, Merril teaches away from using a manikin. In addition, with regards to claim 20(a) (first original claim 20), the cited sections of Gillio and Merril do not teach real-time detection (i.e., that there is essentially no latent period between movement of an actual device and display of a moving virtual image of the device). Gillio and Merril merely disclose their aspiration to provide a realistic simulation.

Merril does not teach a simulated scanning display which is part of a simulated scanning

device. Instead, Merril merely teaches displaying a scanning display on a monitor (see, column 10, lines 33-36).

The Examiner asserts that providing a re-configurable control panel for performing image selection, display, manipulating a table, manipulating the position of a scanning device relative to a manikin and control of one or more shutter devices for limiting a field of view of a scanning device placed within scanning distance of a manikin are features known in the art and would have been obvious. This conclusory statement is completely unsupported. As discussed by the Federal Circuit in *In re Sang-Su Lee,* 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002), "[the] factual question of motivation is material to patentability, and [cannot] be resolved on subjective belief and unknown authority."

With regards to claim 26 (renumbered as claim 27), Figure 13 and the large section of text by Gillio cited by the Examiner does not disclose a monitoring station comprising a second user device connectable to the network and comprising a second display interface for enabling a second user to monitor the movement of the medical device within the simulated body cavity or lumen wherein the second display interface of the monitoring station displays selectable options enabling the second user to select or change one or more anatomical and/or physiological parameters of the simulated body cavity or lumen, and wherein the selection causes the three-dimensional image of the simulated body cavity or lumen displayed to the first user to change to reflect the changed anatomical and/or physiological parameters. To the extent Gillio suggests that simulations can be performed remotely from the interface, Gillio does not disclose providing an interface that would allow a second user to alter a simulation being experienced by a first user at a first interface. Gillio instead merely discloses a performing telesurgery using a virtual mock-up of surgical instruments while a robot in a remote location performs the actual surgery based

on the surgeon's movements relating to the virtual surgical devices (see, column 3, lines 12-26).

With regards to claim 47, at column 16, lines 11-41, Merril does not disclose that the system simulates deformation of a body cavity or lumen by a medical device. Merril only discloses displaying expansion of a balloon (see, column 16, lines 11-14).

The Examiner acknowledges that Merril does not disclose simulating blood vessels of the brain but concludes that it would have been obvious to do so. Applicants traverse the rejection. The blood vessels of the brain are much smaller, more fragile and more prone to spasm than the lumens of cardiovascular blood vessels. When a medical device is inserted in a blood vessel of the brain, because of this tendency to spasm, mere contact with the medical device will tend to cause the vessel to contract and prevent further movement of the device. Modeling of interactions between a device and lumen as required by claim 1 for example, requires modeling both properties of the blood vessels of the brain and the medical device. The disclosure of Merril does not enable one of skill in the art to extrapolate from a simulation of cardiovascular blood vessels to simulation of blood vessels of the brain and/or interactions of a medical device with such blood vessels.

With regards to claim 53, Gillio does not teach providing a medical device comprising a first end for manipulation by a user and a portion comprising a second end inserted into a simulated body cavity or body lumen in a manikin, wherein the simulated body cavity or lumen in the manikin comprises a directional force feedback mechanism, and wherein, in response to a feedback signal, the directional force feedback mechanism creates resistance to forward motion of the medical device but allows free reverse motion. To the extent that Gillio discloses a spring that provides resistance to forward motion (as in Figure 7, in connection with the use of a

joystick), Gillio merely suggests that there is a connection between the spring and processor that somehow provides feedback. However, Gillio does not disclose that *as a consequence of the feedback*, there is *increased* resistance to forward motion. Rather, in Gillio's system, it is merely forward motion of an instrument that results in increased resistance. Additionally, as discussed above, Gillio does not provide any enabling disclosure that would allow one to model interactions between a medical device and the body cavity or lumen of a patient in three-dimensions and Merrill does not remedy this deficiency.

Additionally, contrary to the Examiner's assertion at page 19, paragraph 3 (for which the Examiner provides no support), Merril nowhere discloses a providing a coil and coil wire to a body lumen or cavity in a manikin via a catheter and simulating displacement of the coil from the coil wire using a re-configurable control panel.

Also, contrary to the Examiner's assertion, Merril and Gillio combined do not produce Applicant's invention. Neither Merril nor Gillio's system use a manikin to simulate a medical procedure. Merril teaches away from the use of a manikin and Gillio's system merely provides a box that interfaces with a tube or hose. Neither Merril nor Gillio disclose a mechanism for providing directional force feedback for exerting a directional force on the medical device in response to a feedback signal received by the force feedback mechanism or modeling interactions between a medical device and the walls of a cavity or lumen in three dimensions. Additionally, neither Merril nor Gillio combined disclose the limitations of the dependent claims as discussed above.

Further, throughout the Office Action, the Examiner makes conclusory assertions that it would be obvious to alter the systems taught by both Merril and Gillio as recited to make a more

realistic simulation, using Applicants' own disclosure to form the basis of what would create a more realistic simulation. As discussed by the Federal Circuit in *In re Sang-Su Lee*, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002), "It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher." Id. (citing *W.L. Gore v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 312-313 (Fed. Cir. 1983).

Therefore, in view of the above arguments, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Rejection of Claims 7, 8, and 63 Under 35 U.S.C. § 103(a)

Claims 7, 8 and 63 are rejected under 35 U.S.C. 103(a) as being obvious over Merril in view of Gillio and further in view of U.S. Patent No. 6,231,444 by Goto ("Goto"). The Examiner acknowledges that neither Merril nor Gillio, alone or in combination, disclose or suggest providing continuous vibrational feedback. However, the Examiner asserts that this would have been obvious to an artisan in view of Goto. The Examiner asserts that Goto discloses an analogous controller device wherein a tactile feedback mechanism provides continuous vibration feedback to a user holding a medical device through a continuously rotating motor.

Applicants traverse the rejection. Goto nowhere discloses or suggests simulating a medical procedure, much less using continuous vibration feedback to simulate metabolic processes such as respiration and circulation. Instead, Goto merely discloses an operation device in a *game machine*. Goto is *not* analogous art. Further, one would not be motivated by Merril's

vague aspirational statements that it is a good thing for a simulation device to be realistic to provide a continuously rotating motor to simulate blood flow and respiration. The Examiner improperly uses Applicants' own disclosure to provide motivation to artefactually combine the references. Applicants respectfully submit that the rejection is improper and should be reconsidered and withdrawn.

CONCLUSION

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,

Date: May 1, 2003

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Clean Copy of Claims Presented For Examination Upon Entry of Amendment

1. (Amended) A system for simulating movement of a medical device in a body cavity or lumen of a patient, comprising:

(a) a medical device comprising a first end for manipulation by a user and a portion comprising a second end insertable into a simulated body cavity or body lumen in a manikin; and

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(b) a manikin comprising an interface for receiving the portion comprising the second end and for interfacing with a simulated body cavity or lumen within the manikin, wherein the interface comprises a directional force feedback mechanism for exerting a directional force on the medical device in response to a feedback signal received by the force feedback mechanism

wherein the system models interactions between the device and the body cavity or lumen in three-dimensions.

2. (Original) The system according to claim 1, wherein the directional force feedback mechanism provides resistance to forward motion but enables free reverse motion in response to the feedback signal.

3. (Original) The system according to claim 1, wherein the directional force feedback mechanism comprises a rolling element coupled to the portion of the device comprising the second end and wherein an internal surface of the simulated cavity or lumen in the manikin comprises an oblique slot for receiving the rolling element.

4. (Original) The system according to claim 3, wherein, in response to a feedback signal, forward movement of the second end causes the rolling element to be received by the slot,

thereby causing resistance to further forward motion.

5. (Original) The system according to claim 4, wherein a motor controls movement of the rolling element.

6. (Original) The system according to claim 1, further comprising a tactile feedback mechanism.

7. (Original) The system according to claim 6, wherein the tactile feedback mechanism provides continuous vibrational feedback to a user holding the medical device.

8. (Original) The system according to claim 8, wherein continuous vibrational feedback is provided through a continuously rotating motor in communication with the portion of the device comprising the second end.

9. (Original) The system according to claim 1, wherein a position of at least the second end of the medical device relative to the manikin is continuously tracked.

10. (Original) The system according to claim 9, wherein the medical device comprises an encoder for tracking the translation of the device and an encoder for tracking the rotation of the device.

11. (Amended) The system according to claim 9, wherein the manikin further comprises a tracking unit comprising a light source, a signal processing circuit, and one or more optical sensors, wherein the tracking unit is placed within the interface in optical communication with the device when it is inserted into the cavity or lumen.

12. (Original) The system according to claim 11, wherein light from the light source reflects on the device when inserted and wherein the reflected light is received by the one or more optical sensors.

13. (Original) The system according to claim 12, wherein changes in reflected light received by the one or more sensors is detected by the system, and wherein, in response to this detection, the system simulates movement of the device in real-time on the user display.

14. (Original) The system according to claim 12, wherein two optical sensors are provided which are perpendicular to one another.

15. (Original) The system according to claim 12, wherein the tracking unit is configured in the form of a rail along which the device can move.

16. (Original) The system according to claim 10, wherein one or more additional medical devices comprising a first end for manipulation by a user and a portion comprising a second end for insertion into the simulated body cavity or body lumen, are inserted into the interface and wherein the position of each medical device is independently monitored.

17. (Original) The system according to claim 16, wherein the one or more medical devices are selected from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, optical probe, a drug delivery device, and combinations thereof.

18. (Original) The system according to claim 1, further comprising a table for placing the

manikin thereon, wherein the table comprises a processor connectable to the network.

19. (Original) The system according to claim 18, wherein the system further comprises at least one first user device connectable to the network, the first user device comprising a first display interface for displaying a three-dimensional representation of a simulated body cavity or lumen of a patient.

20. (Original) The system according to claim 19, wherein the first display interface further displays a three-dimensional representation of a medical device corresponding to a medical device which is interfaced with the manikin and wherein the system simulates on the display the movement of the medical device within the simulated body cavity or lumen of the manikin in real-time when a first user manipulates the medical device interfaced with the manikin.

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21. (Amended) The system according to claim 19, further comprising a simulated scanning display for displaying a two-dimensional image of the simulated body cavity or lumen.

22. (Amended) The system according to claim 21, wherein the simulated scanning display is part of a simulated scanning device.

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23. (Amended) The system according to claim 22, wherein the simulated scanning device is simulating an x-ray imaging system.

24. (Amended) The system according to claim 22, wherein the simulated scanning device and scanning display are coupled to a movable C-arm within scanning distance of the manikin.

25. (Amended) The system according to claim 1, further comprising a re-configurable control panel for performing one or more of: image acquisition selection; image display; manipulating a table on which the manikin is placed; manipulating the position of a simulated scanning device relative to the manikin; and control of one or more shutter devices for limiting a field of view of a scanning device placed within scanning distance of the manikin.

26. (Amended) The system according to claim 1 or 20, further comprising a monitoring station, the monitoring station comprising a second user device connectable to the network and comprising a second display interface for enabling a second user to monitor the movement of the medical device within the simulated body cavity or lumen.

A3 27. (Amended) The system according to claim 26, wherein the second display interface of the monitoring station displays selectable options enabling the second user to select or change one or more anatomical and/or physiological parameters of the simulated body cavity or lumen, and wherein the selection causes the three-dimensional image of the simulated body cavity or lumen displayed to the first user to change to reflect the changed anatomical and/or physiological parameters.

28. (Amended) The system according to claim 20, wherein the system is connectable to a database of patient images and/or medical data.

29. (Amended) The system according to claim 26, wherein the system is connectable to a database of patient images and/or medical data.

30. (Amended) The system according to claim 28, wherein the patient images comprise

images of a body cavity or lumen from a patient affected by a pathology.

31. (Amended) The system according to claim 29, wherein the patient images comprise images of a body cavity or lumen from a patient affected by a pathology.

A3 32. (Amended) The system according to claim 22, further comprising at least one foot-activation switch for activating or collimating the simulated scanning device, image display or table movement.

33. (Amended) The system according to claim 28, wherein the first user display interface provides access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the first user display interface.

34. (Amended) The system according to claim 28, wherein the second user display interface provides access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the second user display interface.

35. (Original) The system according to claim 33, wherein the second user display interface provides access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the second user display interface.

36. (Original) The system according to claim 35, wherein the second user display interface provides a selectable option enabling a second user to display the image displayed on the second user display interface, on the first user's display interface.

37. (Original) The system according to claim 1, wherein the device is selected from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, optical probe, a drug delivery device, and combinations thereof.

38. (Amended) A syringe for simulating fluid delivery, comprising:

a housing defining a lumen comprising an opening for delivering a fluid;

a pushing element for pushing the fluid through the opening;

a friction-producing element within the lumen of the housing in communication with the pushing element; and

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a motor within the lumen of the housing and in communication with the friction-producing element and comprising a signal-receiving element,

wherein the friction-producing element causes friction between the pushing element and a surface of the lumen of the housing upon activation of the motor in response to a signal received by the signal-receiving element.

39. (Original) The syringe according to claim 38, wherein the motor, when activated, causes motion of the friction-producing element, thereby causing the friction-producing element to contact the surface of the lumen of the housing, creating friction between the pushing element and the surface of the lumen and resistance to the motion of the pushing element.

40. (Original) The syringe according to claim 38, wherein the friction-producing element comprises one or more rubber pads.

41. (Original) The syringe according to claim 40, wherein each rubber pad is coupled to

an arm whose movement is controlled by the motor.

42. (Original) The syringe according to claim 41, wherein each arm is coupled to the motor through a gear attached to the motor.

43. (Original) The syringe according to claim 38, wherein the amount of friction produced by the friction-producing element is adjusted by controlling a rotation angle of the motor.

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44. (Amended) The system according to claim 1, further comprising a syringe for simulating fluid delivery, the syringe comprising:

a housing defining a lumen comprising an opening for delivering a fluid;

a pushing element for pushing the fluid through the opening;

a friction-producing element in communication with the pushing element; and

a motor in communication with the friction-producing element and comprising a signal-receiving element,

wherein the friction-producing element causes friction between the pushing element and a surface of the lumen of the housing upon activation by the motor in response to a signal received by the signal-receiving element, and further

wherein the opening of the syringe is connectable to a connecting piece having a first end for receiving fluid from the opening and a second end for delivering fluid to a simulated body cavity or body lumen in the manikin.

45. (Amended) A balloon-inflating device for simulating deployment of a balloon within a body cavity or lumen of a patient, comprising:

a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon;

a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device;

an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor and an automatic control system for controlling the amount of pressure delivered to the balloon.

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46. (Amended) The system according to claim 1, further comprising a balloon-inflating device for simulating deployment of a balloon within the body cavity or lumen of the patient, the balloon-inflating device comprising:

a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon;

a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device;

an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor.

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47. (Original) The system according to claim 20, wherein the system simulates deformation of the body cavity or lumen by the medical device.

48. (Original) The system according to claim 20, wherein the system simulates an operation of a medical device selected from the group consisting of: a surgical procedure, inflation or deflation of a balloon, injection of a radioopaque material into the body cavity or lumen, and combinations thereof.

49. (Original) The system according to claim 20, wherein the system simulates the movement of the device within a blood vessel.

50. (Original) The system according to claim 49, wherein the blood vessel is in the brain.

51. (Original) The system according to claim 50, wherein the blood vessel is in the heart.

52. (Original) A method for simulating the movement of a medical device in the body cavity or lumen of a patient, comprising:

providing a medical device comprising a first end for manipulation by a user and a portion comprising a second end inserted into a simulated body cavity or body lumen in a manikin, wherein the simulated body cavity or lumen in the manikin comprises a directional force feedback mechanism, and

wherein, in response to a feedback signal, the directional force feedback mechanism creates resistance to forward motion of the medical device but allows free reverse motion.

53. (Original) The method according to claim 52, further comprising:

providing a system comprising:

a processor in communication with the directional force feedback mechanism, the processor connectable to the network; and

a first user device in communication with the processor, the first user device comprising a first display interface for displaying a representation of a body cavity or lumen; and for providing access to a database of three-dimensional images of body cavities and lumens from a plurality of different patients; and

enabling a user to select from the database a representation, wherein in response to the selection, the representation is displayed on the first display interface.

54. (Original) The method according to claim 52, wherein the first display interface a displays a three-dimensional representation of the medical device and wherein the system simulates the movement of the medical device within the body cavity or lumen in real-time as a first user manipulates the medical device which is interfaced with the manikin.

55. (Original) The method according to claim 52 or 53, further comprising providing a monitoring station comprising a second display interface in communication with the processor and the first display interface, and wherein the second display interface provides a second user with access to the database.

56. (Original) The method according to claim 54, wherein when a second user selects a representation from the database, the representation is displayed on both the first and second display interface.

57. (Original) The method according to claim 53, wherein the system simulates the deformation of a body cavity or lumen in response to movement of the medical device by the first user and displays the representation of the deformation on the first display

interface.

58. (Original) The method according to claim 53, wherein the medical device performs an operation on the simulated body cavity or lumen and the first display interface displays a simulation of the operation.

59. (Original) The method according to claim 58, wherein the operation is inflation or deflation of a balloon within the simulated body cavity or lumen.

60. (Original) The method according to claim 58, wherein the operation is injection of a radioopaque fluid within the body cavity or lumen.

61. (Original) The method according to claim 52, wherein the device is selected from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, an optical probe, a drug delivery device, and combinations thereof.

62. (Original) The method according to claim 54, wherein a first user inserts one or more additional medical devices into the simulated body cavity or lumen, and the movement of each medical device is independently monitored.

63. (Original) The method according to claim 52, wherein the simulated body cavity or lumen in the manikin further comprises a tactile feedback mechanism, providing continuous vibrational feedback to a first user manipulating the device.

64. (Original) A method for simulating fluid delivery into a body cavity or lumen of a patient comprising:

(a) providing a syringe for simulating fluid delivery, the syringe comprising:

a housing defining a lumen comprising an opening for delivering a fluid;

a pushing element for pushing the fluid through the opening;

a friction-producing element in communication with the pushing element; and

a motor in communication with the friction-producing element and comprising

a signal-receiving element,

wherein the friction-producing element causes friction between the pushing element and a surface of the lumen in response to a signal received by the signal receiving element; and

(b) providing a signal, thereby causing friction between the pushing element and the lumen.

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65. (Amended) A method for simulating deployment of a balloon within a body cavity or lumen of a patient, comprising:

(a) providing a balloon-inflating device, comprising:

a delivery mechanism for controlling delivery of a fluid through the balloon-inflating device to the balloon;

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a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device;

an electrical pressure meter for reading pressure determined by the pressure sensor and for transmitting a signal corresponding to a pressure value to a

processor; and

an automatic control system for controlling the amount of pressure delivered to the balloon;

(b) providing a system comprising:

a processor for receiving the signal, the processor connectable to the network; and

a user device comprising an interface displaying a representation of the balloon

within a simulated body cavity or lumen; and

(c) delivering the fluid to the balloon; wherein deployment of the balloon in response to the delivering is displayed on the user device.

66. (Original) The method according to claim 65, wherein the fluid is air.

67. (Original) The method according to claim 65, wherein the method is used to simulate balloon angioplasty.

68. (Original) The method according to claim 65, further comprising providing the system according to claim 1, inserting a balloon catheter into the simulated body cavity or lumen to simulate navigating to a target region of the body, and simulating positioning the balloon deployment device in proximity to the balloon catheter to inflate or deflate the balloon.

69. (Original) The method according to claim 67, further comprising inserting a catheter and guidewire into the body cavity or lumen to navigate the balloon cavity to the target

region.

70. (Original) The method according to claim 67, further comprising inserting a stent catheter to navigate to a target region and using the balloon to deploy the stent, thereby simulating stent deployment in the body cavity or lumen.

71. (Original) The method according to claim 68, further comprising inserting a catheter or guidewire into the body cavity or lumen to navigate the stent catheter to the target region.

72. (Original) A method for simulating coil embolization in a body cavity or lumen of a patient, comprising:

providing a catheter, guidewire and coil wire comprising a coil to navigate to a target region of the body;

providing the system according to claim 19, wherein the re-configurable control panel provides a selectable option for detaching the coil from the coil wire, and wherein selecting the selectable option triggers the release of the coil from the coil wire.

73. (Original) The method according to claim 72, wherein an electrical current triggers release of the coil from the coil wire.

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74. (New) A system for simulating movement of a medical device in a body cavity or lumen of a patient, comprising:

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(a) a medical device comprising a first end for manipulation by a user and a portion comprising a second end insertable into a simulated body cavity or

body lumen in a manikin; and

(b) a manikin comprising an interface for receiving the portion comprising the second end and for interfacing with a simulated body cavity or lumen within the manikin, wherein the interface comprises a feedback mechanism for providing continuous vibrational feedback to the medical device.

A7 75. (New) A system for simulating movement of a medical device in a body cavity or lumen of a patient, comprising:

(a) a medical device comprising a first end for manipulation by a user and a portion comprising a second end insertable into a simulated body cavity or body lumen in a manikin;

(d) a manikin comprising an interface for receiving the portion comprising the second end and for interfacing with a simulated body cavity or lumen within the manikin; and

(e) a processor for simulating real-time movement of the medical device within a simulated body cavity or lumen, wherein deformation of the simulated body cavity or lumen in response to blood flow or the movement of the medical device is modeled in real-time.